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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/391,762	09/08/1999	KEVIN WEADOCK	498-36-RES	9047
23869	7590	11/10/2004	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 11/10/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/391,762

Applicant(s)

WEADOCK ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,7 and 9-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,7 and 9-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2004 has been entered.

***Claim Objections***

Claims 13 and 31 are objected to because of the following informalities:

Regarding claim 13, it appears that the claim is claiming both the intermediate product and the final product so it is unclear which is relevant. The Examiner suggests inserting the language "capable of" before "forming" on line 5 of the claim in order to overcome this objection.

Regarding claim 31, on line 2, the use of the term "crosslinked" is confusing since the intermediate product is being set forth; see base claim 29. Therefore, the Examiner suggests changing "crosslinked" to "crosslinkable" in order to overcome this objection. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 contradicts base claim 13 that requires an acidic solution, yet the present claims attempts to claim a pH-adjusted solution. For this reason, it is unclear which of these two products are being set forth such that claim scope is considered indefinite.

Claims 1-4, 7, and 9-31 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue, which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that Appellant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Present claims 1-4, 7, and 9-31 are improper for a reissue application because they attempt to recapture subject matter surrendered in order to overcome a prior art rejection. Specifically, during the pendency of the patented file 08/289,790, the

language "filled with fluid which solidifies and is crosslinked to form" and "said material being insoluble at a pH of about 7.4" was added in order to overcome a prior art rejection. Therefore, it is improper to attempt to recapture this subject matter via claims 1-4, 7, and 9-31 in the present reissue application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 13-17, 21-25, and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaehler et al (journal article entitled "Precoating Substrate and Surface Configuration . . . "). The following is paraphrased from the Board of Appeals decision rendered July 21, 2003, the rejection of claim 13 on page 8 of the decision. Kaehler describes a vascular graft which comprises a body of PTFE having a structure of spaced-apart nodes interconnected by fibrils having pores present between the fibrils and nodes. The vascular grafts used in Kaehler are reinforced (see Kaehler, page 536, left hand column, "Graft material") which are also described in the '114 patent as being e-PTFE on column 1, lines 56-63. The vascular grafts of Kaehler contain the nodes and fibril structure claimed as seen from a complete reading of Kaehler; see, for example the paragraph bridging the two columns on page 537. The claims require that the implantable member of e-PTFE contains a biodegradable composition of natural origin in its pores. On page 536, Kaehler teaches filling the graft with an acidic solution

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containing collagens I, III, and IV; see the forth full paragraph of the right column. The 0.05 N HCl solution has a pH of 2.0; see CRC handbook of Chemistry and Physics, 64<sup>th</sup> Edition (1984), page D-151. After the pores are filled with the 2.0 pH solution of collagen, the graft is rinsed with water and PBS (i.e. phosphate buffered saline) to remove the acid which inherently changes the pH to near neutral (pH 7.0) since the acid has been removed. For these reasons, the claim limitations are fully met because even the same method of making is used. Therefore, the alternative 103 rejection is not needed; see MPEP 2113.

Regarding claim 17, PBS is phosphate buffered saline; see the 4<sup>th</sup> full paragraph of the left column of page 536.

With regard to claim 31, since the same collagen material is used as that claimed and disclosed by Applicant, the Examiner asserts that the claim language is fully met since it would inherently capable of being treated as such.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaehler (journal article entitled "Precoating Substrate . . . ") in view of Hoffmann (US 5,197,977). Kaehler meets the claim language as explained *supra* but fails to disclose the use of a pharmacological agent as claimed. However, Hoffmann

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teaches that it was known to use pharmacological agents in similar grafts within the art; see the paragraph bridging columns 5 and 6. Therefore, it would have been considered prima fascia obvious to an ordinary artisan to include a pharmacological agent in the Kaehler implant for the same reasons that Hoffmann teaches doing the same.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaehler (journal article entitled "Precoating Substrate . . .") in view of Tran et al (article entitled "Plasma Modification. . ."). Kaehler meets the claim language as explained supra, but fails to teach modifying the substrate to enhance its hydrophilic character (claim 11) by subjecting the polytetrafluoroethylene to plasma deposition (claim 12). However, Tran also describes polytetrafluoroethylene grafts, which are coating with collagen, and which have been pretreated to make them more hydrophilic by plasma deposition; see page 374 and page 379 including Table III. Therefore, it would have been considered prima fascia obvious to an ordinary artisan to pretreat the graft of Kaehler to make is hydrophilic via plasma deposition to render the graft more receptive to collagen impregnation as taught by Tran.

Claims 18 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaehler et al (journal article entitled "Precoating Substrate . . .") in view of Alonso (US 5,037,377). Kaehler meets the claim language as explained in the Section 102 rejection *supra*, but fails to disclose the pH of the phosphate buffer as claimed. However, Alonso teaches the phosphate buffers having pH's of 7.4 were known to the same art; see column 3, lines 31-41. Therefore, it is the Examiner's position that it

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would have prima fascia obvious to an ordinary artisan to use a 7.4 pH phosphate buffer for the same reasons that Alonso uses the same.

### ***Response to Arguments***

Applicant's arguments with respect to the present claims have been considered but are moot in view of the new ground(s) of rejection. The Examiner has further explained and modified the rejections such that the arguments set forth in the response are considered moot or at least addressed by the new explanation provided in the rejections.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should



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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic  
Primary Examiner  
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